

REMARKS

Claims 1-11, 14-22, 25-34 are pending and under examination in the above-identified application. Claims 12, 13, 23, 24, 35 and 36 have been previously canceled and claims 2, 3, 11, 29 and 30 are canceled herein. Applicants reserve the right to pursue these claims in a later filed application claiming the benefit of priority of the above application. Claims 1, 4, 5, 6, 14, and 28 have been amended above. Support for the amendments to claims 1, 14 and 28 can be found in the specification at, for example, paragraphs [023], [054]- [055] and [098] and in claims 3, 11 and 30. Support for the amendments to claim 14 can be found in the specification, for example, in original dependent claims 25, 26 and 27 and in the specification at paragraphs [035]-[036] and [055]. The amendments to claims 4 and 5 correct antecedent basis. Dependent claims 37 and 38 have been added above. Support for the new claims can be found at paragraphs [023], [054], [055] and [071]-[072]. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested. Applicants have reviewed the rejections set forth in the Office Action mailed April 26, 2007, and respectfully traverse all grounds for the reason that follow.

Rejections Under 35 U.S.C. § 102

Claims 14, 15, 17, 19, 21, and 22 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Chenchik et al., WO 99/35289, (Chenchik et al.), because Chenchik et al. allegedly discloses an array composition comprising a substrate having sites, each site comprising a plurality of different target analytes, comprising sequences from different individuals, wherein the targets are covalently attached to the substrate. The analytes in the array allegedly can be either proteins or nucleic acids. In addition, the array can allegedly be made of plastic, with the discrete sites being wells.

When the lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)).

While not conceding that Chenchik et al. describe the invention of claims 14, 15, 17, 19, 21 and 22, claim 14 now recites that the claimed array composition includes discrete sites at a density of about 10000 to 1,000,000,000 per square centimeter. This element is supported by original dependent claims 25, 26, and 27, all of which depend from claims 1 or 14, and which have been deemed to be distinguishable from Chenchik et al..

Chenchik et al. does not recite an array composition with a target density within the claimed range. Rather, Chenchik et al. teaches densities that are significantly lower than the claimed densities:

The density of the spots of the solid surface in certain embodiments is at least about $5/\text{cm}^2$ and usually at least about $10/\text{cm}^2$ but does not exceed about $1000/\text{cm}^2$, and usually does not exceed about $500/\text{cm}^2$, and more usually does not exceed about $300/\text{cm}^2$.

Chenchik et al., WO99/35289 at p. 7, lines 19–22 (emphasis added).

Since Chenchik et al. does not disclose the range element of claim 14, this reference fails to teach all elements of the claim. Therefore, Chenchik et al. cannot anticipate claim 14. Similarly, as dependent claims 15, 17, 19, 21, and 22 all depend from claim 14, and thus include all elements recited therein, Chenchik et al. also cannot anticipate these claims. For the foregoing reasons, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 14-15, 17, 19, 21-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chenchik et al., U. S. Patent No. 6,087,102 (Chenchik `102). The Office alleges that Chenchik `102 describes an array composition comprising a substrate having discrete sites, each site comprising a plurality of different target analytes comprising sequences from different individuals wherein the targets are covalently attached to the substrate. In addition, the Office alleges that Chenchik `102 discloses an array wherein the targets can be either nucleic acids or proteins, the substrate is plastic, and wherein the discrete sites on the array are wells. However, no reason or rationale is provided for why the `102 Chenchik et al. patent teaches or suggests the claimed invention.

To establish a *prima facie* case of obviousness, the Office must show that the prior art would have suggested the claimed invention to one of ordinary skill in the art and that it could have been carried out with a reasonable likelihood of success when viewed in the light of the prior art. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000), *accord In re Royka*, 180 USPQ 580 (C.C.P.A. 1974) (to establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art); M.P.E.P. § 2143.03

The Office has not met the burden of establishing a *prima facie* case of obviousness. The Office has given no reasons as to why Chenchik `102 would have taught or suggested to one skilled in the art how to make the invention as claimed. Absent some reason or explanation why the `102 patent would have led one skilled in the art to arrive at the claimed invention, the Office has failed to meet its burden.

Nevertheless, while not conceding that Chenchik `102 teaches or suggests the invention of claims 14, 15, 17, 19, 21 and 22 obvious, claim 14 now recites that the previously claimed array composition includes discrete sites at a density of about 10000 to 1,000,000,000 discrete sites per square centimeter. This element is supported by original dependent claims 25, 26, and 27, all of which depend from claim 1 or 14 and which have been deemed to be distinguishable and unobvious over the Chenchik `102.

Chenchik `102 does not recite an array composition with a target density within the claimed range. Although Chenchik `102 teaches an amount of sample to place in a slot of the gel arrays described therein (see, e.g., Chenchik et al., U.S. Pat. No. 6,087,102 at col. 5, lines 8-13) there is no description of a density of discrete sites, much less the density recited in the claims. Therefore, Chenchik `102 is silent as to density of discrete sites per square centimeter.

Since Chenchik `102 does not disclose the range of site densities of claim 14, it fails to teach or suggest all elements of the claim. Similarly, as dependent claims 15, 17, 19, 21, and 22 all depend from claim 14, and thus include all elements recited therein, the `102 Chenchik et al. patent also cannot teach or suggest all elements of these claims. Absent some teaching or suggestion of all claimed elements, the `102 Chenchik et al. patent cannot render the invention of claims 14, 15, 17, 19, 21, and 22 obvious. Withdrawal of this ground of rejection is respectfully requested.

Claims 1-2, 5, 7-8, 10-11, 28-29 and 34 stand rejected under 35 U.S.C. 103(a) as being obvious over Walt et al., WO 98/40726, (Walt `726) in view of Chenchik `102 or Pinkel et al., U.S. Patent No. 5,830,645 (Pinkel et al.). The Office alleges that Walt `726 describes all elements of independent claims 1 and 28, except for covalent attachment of the target analytes from first and second individuals. Pinkel et al. and Chenchik `102 are alleged to describe covalent attachment from different sources.

Applicants respectfully point out that the passages relied on by the Examiner in Chenchik `102 and Pinkel et al. are silent as to covalent attachment of different target analytes from different individuals to each microsphere. Accordingly, absent some teaching or suggestion of different target analytes the cited combination cannot render the invention as claimed obvious.

Nevertheless, while not conceding that Walt `726 in combination with Chenchik `102 or Pinkel et al., render the claimed invention obvious, independent claims 1 and 28 now recite the elements of original dependent claims 3 and 30, deemed to be distinguishable from Walt `726 and Chenchik `102 or Pinkel `645 and claim 14 now broadly recites elements from dependent claims 25-27, deemed to be distinguishable from Walt `726 and Chenchik `102 or Pinkel `645. Therefore, in light of this amendment this ground of rejection is moot and its withdrawal is respectfully requested.

Claims 1-2, 5-11, 14-22, 25-29, 32-34 stand rejected under 35 U.S.C. 103(a) as being obvious over Walt et al., U.S. Patent No. 6,327,410, (Walt `410) in view of Chenchik `102) or Pinkel et al.. The Office alleges that Walt `410 describes all elements of independent claims 1, 14 and 28, except for covalent attachment of the target analytes from first and second individuals, which is alleged to be described by Pinkel et al. and Chenchik `102.

Applicants again respectfully point out that the passages relied on by the Examiner in Chenchik `102 and Pinkel et al. are silent as to covalent attachment of different target analytes from different individuals to microspheres of each microsphere. Accordingly, absent some teaching or suggestion of different target analytes the cited combination cannot render the invention as claimed obvious.

Nevertheless, while not conceding that Walt `410 in combination with Chenchik `102 or Pinkel et al., render the claimed invention obvious, independent claims 1, 14 and 28 now recite the elements of claims 3 and 30 deemed to be distinguishable from Walt `410 and Chenchik `102 or Pinkel `645. In light of the above, this ground of rejection is moot and its withdrawal is respectfully requested.

Claims 1-11, 14-22, 25-34 stand rejected under 35 U.S.C. 103(a) as being obvious over Chee et al., U.S. Patent No. 6,355,431, (Chee `431) in view of Chenchik `102 or Pinkel et al. The Office alleges that Chee `431 describes all elements of independent claims 1, 14 and 28, except for covalent attachment of target analytes from first and second individuals, which is alleged to be described by Pinkel et al. and Chenchik `102.

Applicants respectfully submit that Chee `431 is disqualified as cited art under 35 U.S.C. § 103(c). Subject matter which would otherwise be cited art to the claimed invention is not available as potential prior art if the claimed invention and the art is commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention was made. *Id.*

Statement of Common Ownership

The subject application, serial no. 10/759,576, and Chee `431 were, at the time the invention of application serial no. 10/759,576 was made, owned by, or subject to an obligation of assignment to, the same person.

Therefore, Chee `431 is disqualified as cited art against the instant application as a basis for obviousness. Withdrawal of this ground of rejection is respectfully requested.

Dependent claims 3, 4, 30 and 31 stand rejected under 35 U.S.C. 103(a) as being obvious over Walt `410 in view of Chenchik `102 or Pinkel et al., as applied to claims 1 and 28, and in further view of Dower et al., U.S. Patent No. 5,770,358, (Dower et al.). The Office alleges that Walt `410 describes all elements of independent claims 1 and 28, except for the use of nucleic acid identifier binding ligands, which are allegedly taught by Dower et al.

Claims 3 and 30 have been canceled. Claims 1 and 28 have been amended to include the elements from claims 3 and 30, respectively. Therefore, Applicants will address the rejection insofar it relates to amended claims 1 and 28 and claims 4 and 30. Independent claims 1 and 28 recite a population of microspheres containing a first and a second microsphere having a plurality of different target analytes from first and second different individuals, respectively. Each microsphere having an identifier binding ligand different from the other microsphere and which identifies the plurality of different target analytes from the first and second individuals, respectively. Thus, the invention claims an array composition where different identifier binding ligands identify a plurality of target analytes from different individuals. The cited combination of references fail to teach or suggest first and second microspheres each having a plurality of target analytes from different individuals that are identified by different identifier binding ligands.

Chenichar '102 and Pinkel et al. are cited for allegedly describing covalent attachment of target sequences. The Office concedes that Walt et al. do not teach an array or composition having a nucleic acid identifier binding ligand. Accordingly, there is no teaching or suggestion of linking an identifier binding ligand to a plurality of target analytes from an individual where the identifier binding ligand identifies pluralities of different target analytes from different first and second individuals. Dower et al. is similarly absent such a teaching or suggestion. Rather, Dower et al. describes the use of tags to mark individual sequences, not a plurality of targets from an individual. The cited passage in Dower et al. is directed to a method of random oligomer synthesis and, therefore, cannot teach or suggest the claimed invention. With respect to marking oligomers, Dower et al. describe the use of tags to identify the sequences of such randomly synthesized oligomers. For example, Dower et al. describe:

[T]he oligomers comprising the library also are attached to an identifier tag that can be easily decoded to report the sequence of each oligomer. The identifier tags may be attached either to the oligomer or to the solid support to which the oligomer is attached.

Id., col. 11, lines 46-54, section entitled "Method for Producing Tagged Synthetic Oligomer Libraries" (emphasis added).

Because Dower et al. describes the use of tags to mark individual sequences Dower et al. cannot teach or suggest an identifier binding ligand that identifies a plurality of target analytes from a population. Nor do Chenchik `102, Pinkel et al., Walt et al. and Dower et al. provide any hint that would have prompted one of ordinary skill to combine the claimed invention because none of the references teach or suggest using an identifier binding ligand to identify a plurality of target analytes from an individual and because Dower et al. teaches that tags are used to distinguish particular sequences. Applicants respectfully submit that no reason to modify the cited art to arrive the invention as claimed exists. Applicants therefore, respectfully submit that the claimed invention is unobvious over the cited art.

Obviousness-Type Double Patenting Rejection

Claims 1-11, 14-22, 25-34 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 21-35 of U.S. Patent 6,355,431 in view of Chenchik et al. or Pinkel et al. Although the claims are not identical, the Office alleges that the `431 patent describes a composition of microsphere populations on a substrate having capture probes attached to them. It is further alleged that the claims differ in that the instant claims refer to analytes, further defined as proteins or nucleic acids, but that the genus of capture probes recited in the `431 patent is small enough such that the proteins or nucleic acids would have been obvious. Further, although the `431 patent does not claim covalent attachment of the capture probes, Chenchik et al. and Pinkel et al. are alleged to do so and it is further alleged that one skilled in the art would have been motivated to combine the references to make the instant invention.

Applicants submit that pending claims 1-11, 14-22 and 25-34 and new claims 37-41 are unobvious over claims 21-35 of U.S. Patent 6,355,431 at least because the claims in the subject application do not recite the subpopulation of different analytes attached to each microsphere in the instant application. Nevertheless, Applicants submit herewith a terminal disclaimer over claims 21-35 of U.S. Patent No. 6,355,431. In view of the terminal disclaimer, Applicants respectfully request that the Examiner withdraw this rejection and all the case to proceed to issuance.

Claims 1-11, 14-22, 25-34 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-18 of U.S. Patent 6,544,732 in view of Chenchik et al. or Pinkel et al. Although the claims are not identical, the Office alleges that the '732 patent describes a composition of microsphere populations on a substrate, the microspheres bearing two analytes. It is further alleged that the claims differ in that the claims refers to microspheres as nanocrystals. It is alleged that the instantly claimed microspheres are generic to the patent nanocrystal microspheres and thus the claims are not patentably distinct. Further, although the '732 patent does not claim covalent attachment of the target sequences, Chenchik et al. and Pinkel et al. are alleged to do so and it is further alleged that one skilled in the art would have been motivated to combine the references to make the instant invention.

Applicants submit that pending claims 1-11, 14-22 and 25-34 and new claims 37-41 are unobvious over claims 1-18 of U.S. Patent 6,544,732 at least because the claims in the subject application do not recite the subpopulation of different analytes attached to each microsphere in the instant application. Nevertheless, Applicants submit herewith a terminal disclaimer over claims 1-18 of U.S. Patent 6,544,732. In view of the terminal disclaimer, Applicants respectfully request that the Examiner withdraw this rejection and all the case to proceed to issuance.

Claims 1-11, 14-22, 25-34 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-30 of U.S. Patent 6,429,027 in view of Chenchik et al. or Pinkel et al. Although the claims are not identical, the Office alleges that the '027 patent describes a composition of a microsphere populations on a substrate, the microspheres bearing two analytes. It is alleged that the instant claims merely differ by terminology used to describe the analytes and, thus, are not patentably distinct. Further, although the '027 patent does not claim covalent attachment of the target sequences, Chenchik et al. and Pinkel et al. are alleged to do so and it is further alleged that one skilled in the art would have been motivated to combine the references to make the instant invention.

Applicants submit that currently pending claims 1-11, 14-22 and 25-34 and new claims 37-41 are unobvious over claims 11-30 of U.S. Patent 6,429,027 at least because the claims in the subject application do not recite the subpopulation of different analytes attached to each microsphere in the instant application. Nevertheless, Applicants submit herewith a terminal

disclaimer over claims 1-30 of U.S. Patent 6,429,027. In view of the terminal disclaimer, Applicants respectfully request that the Examiner withdraw this rejection and all the case to proceed to issuance.

Claims 1-5, 28-31 stand rejected under the judicially created doctrine of obviousness-type double patenting over claim 14 of U.S. Patent 6,620,584 in view of Chenchik et al. or Pinkel et al. Although the claims are not identical, the Office alleges that the '584 patent describes a composition of microsphere populations on a substrate, the microspheres bearing two analytes. It is alleged that the instant claims merely differ by an arrangement of limitations and, thus, are not patentably distinct. Further, although the '584 patent does not claim covalent attachment of the target sequences, Chenchik et al. and Pinkel et al. are alleged to do so and it is further alleged that one skilled in the art would have been motivated to combine the references to make the instant invention.

Applicants submit that currently pending claims 1-11, 14-22 and 25-34 and new claims 37-41 are unobvious over claim 14 of U.S. Patent 6,620,584 at least because the claims in the subject application do not recite the subpopulation of different analytes attached to each microsphere in the instant application. Nevertheless, Applicants submit herewith a terminal disclaimer over claim 14 of U.S. Patent 6,620,584. In view of the terminal disclaimer, Applicants respectfully request that the Examiner withdraw this rejection and all the case to proceed to issuance.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

Application No.: 10/759,576

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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